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The first year of the Project has been a development and design year. The goal of this year, as outlined in the Statement of Work (Proposal page 18) was to establish data collection procedures. The tasks outlined to accomplish this goal included: 1) negotiate data collection procedures and standardized forms with all mammography sites, 2) train cancer registrars to complete data forms for all breast tissue specimens, 3) establish computer database structures, key entry procedures and data management routines, 4) develop a liaison with New Hampshire State Registry staff for tumor registry data transfer, 5) develop a liaison with New Hampshire Department of Health and Human Services for vial records transfer. We were successful in achieving the above stated goals. The specific details of our accomplishments are outlined in this report.

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E P Sheehan 10/23/95

PI - Signature Date

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INTRODUCTION

The long-term objective of this Project is to improve the health of New Hampshire women by improving screening and detection of breast cancer. To accomplish this, the New Hampshire Mammography Network proposed to implement a comprehensive database tracking system, which will allow us to follow the outcomes of women receiving mammography (either diagnostic or screening) over time. We will link demographic and risk factor information we obtain from women with radiologists and pathologists' reports. For individuals who are diagnosed with breast cancer, we will link their data with the tumor registry to obtain outcomes through first course of treatment and vital statistics data to match cases with morbidity data.

New Hampshire (N.H.) is well suited to population-based research. It has a stable population with a blend of urban and rural communities and has a relatively high level of literacy (82.2% of New Hampshire adults are high school graduates), which simplifies interviewing and form completion. New Hampshire is also a relatively small state with an estimated population of 1,136,000 (1). Breast cancer is the leading cancer in N.H. women with over 600 cases per year, representing 33% of all female cancers (2). the mortality rate is 29 per 100,000, which is higher than the national rate of 27.3 per 100,000 (3). Women between the ages of 40 and 74 represent about 14% of the population, numbering 160,000 (1). Data from 1991 on the behavioral risk factors of N.H. women revealed that 37% of women between the ages of 40-49 report that they have not had a mammogram within the past two years and 50% of women over age 50 report that they have not had a mammogram within the past year (4). Clearly, the development of a population-based mammography registry would be an important contribution to understanding the problem of breast cancer in New Hampshire.

The first year of the Project has been a development and design year. The goal of this year, as outlined in the Statement of Work (Proposal page 18) was to establish data collection procedures. The tasks outlined to accomplish this goal included: 1) negotiate data collection procedures and standardized forms with all mammography sites, 2) train cancer registrars to complete data forms for all breast tissue specimens, 3) establish computer database structures, key entry procedures and data management routines, 4) develop a liaison with New Hampshire State Registry staff for tumor registry data transfer, 5) develop a liaison with New Hampshire Department of Health and Human Services for vial records transfer. We will address in the Methods and Materials Section of this report the progress we have made in accomplishing these tasks in two sections: Project Development and Registry Design.

METHODS AND MATERIALS

• Project Development

After funding was approved, the details of the Project were presented at the biannual meeting of the N.H. Radiological Society (ACR Chapter) in October 1994.

Volunteers were solicited to serve on an advisory committee to the central research staff. Seven radiologists representing five community-based hospital mammography facilities volunteered to serve on the advisory committee and to allow pilot testing to occur at their facilities. The advisory committee is, therefore composed of these seven volunteers and the research team, including E. Robert Greenberg, MD, Principal Investigator, Patricia A. Carney, PhD, Project Director, Steven P. Poplack, MD, Radiology Liaison, Wendy A. Wells, MD Pathology Liaison. The Project was also subsequently endorsed formally by both the NH Radiological Society and the N.H. Society of Pathologists. The Advisory Committee meets every four months to review progress and set policies and procedures for the registry. With this committee and the research team fully in place, the first task, that of negotiating data collection procedures and standardized forms with all mammography sites, was addressed.

Site visits were made to all 46 mammography facilities in the state. The majority of these were made by the Project Director (80.%), with the remaining (20%) made by the Radiology Liaison. The objectives of these visits were to outline the project activities more fully, enlist the support of radiologists, technologists, and pathologists, determine the characteristics of mammographic facilities and identify and attempt to address potential concerns. Data were collected through structured interviews using a standardized data collection instrument. the entire visit took about 60 minutes to complete.

Though all mammography facilities were visited, one center declined to provide site specific information. Data presented here are based on information obtained from the remaining 45 sites. Because delineation between screening and diagnostic mammography is necessary in defining positive predictive values, we queried facilities about how this delineation is made. We found that 44% of the facilities use patient self-report, 38% use the requisition from the referring physician, and in the remaining 18% of the cases, the radiologist at the facility makes this determination after the mammogram is interpreted. There are only five (11%) facilities which perform screening mammography exclusively.

We further learned that eighty-one of the 103 radiologists in New Hampshire (79%) read mammograms. The majority of these radiologists practice in group associations with membership between three and eight, with a mean of four. In exploring the reporting practices of radiologists, we discovered that while the majority of facilities had computers (71%), most of these were used for billing purposes only. DOS-based computer systems predominated (89%), with Macintosh™-based systems in the remaining 11% of facilities with computers. Relatively few (16%) facilities had Radiology Information Systems or Hospital Information Systems (38%), which would allow them access to comprehensive patient information.

We found that 91% of radiologists generate mammography reports using free-style dictation only, 7% use a combination of computer generated and dictated reports, and the remaining 2% used computer generated reports only. While 49% use a system to categorize reports, only 11% use the ACR categories. Despite the lack of utilization of

the ACR Lexicon, there was general agreement to adopt the lexicon assessment and recommendation terminology for project purposes. Furthermore there was enthusiasm to standardize mammography reporting in general.

We investigated notification processes by stratifying reports based on the mammographers degree of concern. We found that 16% of facilities have a system that reminds either patients or their primary care providers about when routine mammograms are due. Only five facilities (11%) notify non self-referred patients of normal results. All facilities notify the referring physician when a mammogram is abnormal, the majority of facilities use the mail (93%) and the remainder initially by telephone with mail follow-up. Again only five facilities notify non self-referred patients by mail of abnormal findings. The number of radiologists who notify patients of abnormal results immediately following the mammogram was not assessed. All facilities routinely contact the requesting physician when a biopsy is recommended; 58% do so by telephone and the remaining 42% do so by mail.

The practice of auditing interpretive results was queried. All sites document pathology results obtained at their institution on mammograms for which biopsy is recommended. The mammography technologists perform this correlation at 80% of facilities, and radiologists do so in the remaining 20%. Only 7% of facilities track the subsequent outcome of indeterminant or suspicious reports for which biopsy results are not readily available. The majority of these audits (91%) are recorded manually (notebook or card file), with only about 9% of facilities using a computer system. Only 4% have a system in place to analyze the outcome of every mammographic encounter and generate a statistical report. None of the facilities have the ability to rigorously track the outcome of negative mammograms. This information is only available when a patient is subsequently biopsied for a palpable abnormality at the same institution, or anecdotally in smaller communities where the facility staff is familiar with the patient.

All breast specimens are processed, sectioned and stained (standard hematoxylin and eosin) for diagnosis in N.H. hospitals, with 56% of facilities handle processing of specimens on site. Some frozen sections are sent to outside labs. When there is adequate tissue, tumor cell estrogen and progesterone receptor protein analysis is performed biochemically by out-of-state commercial laboratories. When diagnostic tissue is limited, 57% of the N.H. pathology laboratories send tissue blocks to a large regional medical center for immunohistochemical analysis of tumor cell estrogen and progesterone receptor protein. The remaining 43% perform similar immunohistochemical studies in their own laboratories or use a commercial laboratory. For 42% of facilities, especially those in rural areas, pathology is read elsewhere, which means that for almost half the facilities, pathology follow-up takes place sometimes over significant distances.

• Concerns Addressed in the Design Phase

The most common concerns raised by mammography facility staff included accuracy of data, confidentiality of data (attendant medico-legal implications), and the

direct and indirect costs (time spent) of project participation. Radiologists feared that data would not truly reflect their interpretive acumen. Both the accuracy of data entry and the statistical reliability of data was questioned.

Radiologists were universally concerned that project participation had the potential to expose their practice to damaging legal or public scrutiny. Some feared that plaintiff council could access the database and acquire the interpretive results of a particular radiologist in an attempt to demonstrate substandard care. Others were alarmed that collective (statewide) interpretive data would be used by plaintiff council to establish standard of care norms which would facilitate malpractice claims or that plaintiff council could select collective data over a particular time range or community profile to establish a false standard which overestimates the accuracy of mammography. Lastly some practices feared that data would be misused by a particular mammography facility for marketing purposes. These same issues were shared by office managers and administrators.

Fears also centered on the additional workload encompassed by data acquisition and management and the cost of these services. In our experience, there was a clear consensus that facilities were operating with the minimal staff required to perform day to day functions, and that additional time spent on data collection for the project would result in significant expense to the facility and radiology practice. Technologists were worried that collecting patient data for the study would require duplication of effort already performed by completing site specific patient intake forms. This consideration was taken into account in the design of technologist forms outlined in Registry Design. Radiologists were concerned that even minimal time spent on data entry could become significant in the setting of large mammographic volumes. For example, if the radiologist interpretation form took 3 minutes to complete this would add 90 minutes of uncompensated time over the course of the day assuming 30 mammograms were interpreted. Radiologists were reassured to learn that acquisition for radiologist interpretation was targeted for less than 1 minute. In addition, facilities were informed that both manual (paper) and computer assisted data collection options would be made available. Many sites were particularly interested in pursuing computerized systems both to limit the handling of multiple data collection instruments and as a means of performing an internal interpretive audit of their practice. No matter how comprehensive the NHMN data set is, there will still be missing data on patients who live out of state or refuse to participate in the study.

Though we initially planned to recruit and train tumor registrars to abstract data on breast tissue pathology, we soon realized that this was not realistic due to the difficulty identifying cases where breast tissue was biopsied and found not to be cancerous and subsequent lack of availability of these data to tumor registrars. We revised our plan to work directly with pathology labs and decided, at the same time, to incorporate a pathology quality assurance program into our development plans. An opportunity arose to recapture State funding for this specific purpose (See Appendix A). Briefly, the goals of this pathology quality assurance program are two-fold. First, we will conduct an assessment of variability in slide preparation, sample sources, and

pathologic reporting, which will assist us in determining possible sources of discordance. Second, we will implement a quality assurance program that includes implementing a standardized reporting system and joint review of slides to enhance the diagnostic accuracy (quality and reproducibility) of breast pathology. Slides from breast tissue biopsies will be randomly selected and sent to participating laboratories in blinded fashion. Slides will be sent around twice to assess inter- and intra observer variability. This will occur both prior to and after implementing a standardized reporting and feedback system for pathologists statewide.

Determining the degree of inter- and intra observer variability in pathology readings as well as factors that may be related to this will assist us in developing a program to enhance diagnostic accuracy in breast pathology. The importance of such a program for New Hampshire women lies in the potential increase in mammographic screening effectiveness potentially resulting in a decrease in breast cancer related morbidity and mortality. The goals of this proposed project are completely in line with New Hampshire's state-wide mammography program, however, funding to undertake this level of pathology assessment was not part of the original proposal. When news that the State was successful in recapturing funding for this Project, Wendy Wells, MD the pathology liaison visited each laboratory in N.H. and met with pathologists to describe and discuss this additional project. By the end of this project, breast pathology reports (benign and malignant) will be standardized, allowing for data extraction at the central data repository (See Appendix E). Data are collected include: source of current breast specimen, diagnostic interpretation, and if malignant data on grade, size, margins, and nodes involved.

- **Registry Design**

While the facility site visits were occurring, instrument and database development were underway. Members of the research team have been participating in the National Cancer Institute funded Breast Cancer Surveillance Consortium, which is group of nine projects with similar goals all of which have received federal funding (Centers for Disease Control, National Cancer Institute, Dept. of Defense). Because our funding began at about the time this Consortium was developed, we were able to design our study instruments around a set of core and optional variables being collected by other Consortium sites. Though an overall approach to the design of the registry was envisioned at the time of the funding proposal, the specifics of data acquisition and implementation were influenced by the responses of mammography facilities to the site visits and participation in the Consortium. It was clear from the outset that the success of the registry depended on the cooperation and participation of mammography facilities and radiologists.

• Response to Concerns Expressed

Confidentiality

To address the concerns of confidentiality of patients, radiologists and pathologists, the New Hampshire Mammography Network Project was reviewed by the State Health Commissioner and was granted protection from litigation under N.H. Statute: RSA 126-A:4a. In addition, Institutional Review Board Approval was obtained for the Project and consent forms outlining specifically what participation would involve and how data would be handled were obtained from radiologists and pathologists as well as from women coming in for mammography. We are currently exploring making application for a Certificate of Confidentiality under Section 301(d) of the Public Health Service Act to provide further federal protection for data that may cross state lines.

Accuracy of Data

Participants were reassured that manually entered interpretive data would be double entered and checked for discrepant results. Any discrepancies will be brought to the attention of the data manager who will resolve the discrepancy by direct site follow-up. The issue of statistical reliability was presented in the context of a relatively small number of mammographic interpretations in which, by chance alone, there happened to be one or more false negative interpretations which would skew the analysis. We have addressed this concern by including confidence limits in the analysis of data that is fed back to each site and each radiologist. This methodology will account for random variability which could influence interpretive results.

Time Spent and Other Form Completion Issues

In order to minimize time of data acquisition, a multi-part system requiring primary input from four different sources was created. Participating women, mammography technologists, radiologists, and pathologists each input data separately. We will eventually integrate data from both the N.H. State Tumor Registry on staging and initial treatment as well as mortality data from the N.H. Department of Vital Statistics when the project becomes completely operational. The development of data acquisition instruments for women, technologists and radiologists has been an iterative process which has occurred both prior to and during pilot testing. All forms have been developed with optical character recognition capability for data entry via scanner (Appendices 2-5). The data are entered into a relational database that allows for tracking by both breast and by woman.

The participant form (See Appendix B) includes: obtaining consent for participation, the patient's perception of why the mammogram is being done, assessment of health status, and demographic information. Obtaining active consent was deemed necessary by our Institutional Review Board due to the need to gain access

to medical records for follow-up purposes over time. This form takes approximately 3-7 minutes for most women to complete.

In our design phase we responded to the technologists concerns about duplication of effort by incorporating each site's intake data into the project technologist form presented in a 2 copy no carbon return format (See Appendix C). The copy would be kept with the patients record and the original sent to the central data repository. Mammography technologists collect information on current breast symptoms and hormonal status, breast surgical history, and a breast cancer risk factor profile. This form now takes approximately 3 minutes to complete and again is designed to take the place of similar forms facilities currently use, resulting in a standardization of data reflected in patients chart. The speed by which this form can be completed was increased when all negative responses were positioned along the left hand margin of the page. This way flow moves directly down if women are asymptomatic and have no breast surgical history or breast cancer risk factors.

The radiologist's form ascertains indication for the exam, breast composition, an assessment and recommendation based on the ACR lexicon (See Appendix D). This form tracks indications, assessment and recommendations by breast and takes approximately 10 seconds to complete for normal mammograms, which make up approximately 85-90% of all mammograms based on current pilot test data. To decrease form completion time, indications, assessment and recommendations for both breasts is made along the left hand border of the form with its completion occurring directly downward for normal mammograms. A brief description of suspicious and malignant breast findings are prospectively collected on the back side.

Database Development

We developed two completely separate databases to manage the registry. One is a patient registration system that allows us to keep track of consenting and non-consenting women (we do not collect or enter data on non-consenting women, we just keep a tally). The patient registration system allows us to monitor the completeness of data received from facilities, generate status reports for them and institute tracking plans for missing data. The database that houses the registry is a relational database that allows us to follow the outcomes of women by breast and by mammogram over time. The patient registration system generates a unique encrypted code that is used as the patient identifier in the registry database. The data in the two systems are always kept completely separate, and back-up systems ensure that no data is deleted or lost. The patient registration system is currently well developed and the relational registry database is currently in beta test mode.

Two community-based and one acute care hospital mammography facilities volunteered to allow us to pilot test data collection instruments and processes we developed. A Project site manual was developed, which outlined specific procedures to be followed as part of data collection. The Project Director and Field Coordinator visited each pilot site reviewed the procedures developed and use of the draft

instruments. Each facility decided on a start date and pilot data collection began. To date we have collected data on more than 2,000 women. Pilot facilities are providing us with complete information more than 90% of the time, and we are currently testing strategies to improve completeness using a receipting system and for following up on missing information. Almost 99% (98.4%) of the women coming in for screening at pilot facilities have agreed in writing to take part in the Project.

Because we believe computerized systems will prove to be a viable option for facilities and will reduce entry costs for the registry, we investigated the computerized mammography management systems which are commercially available as well as several in development. Essential features required by the project data base included: identifying and demographic data, risk factor profile, mammography encounter history, breast surgical history, current breast symptoms, mammography reporting information described with ACR lexicon terminology, ease of use, fiscal affordability, and export function. We also identified several non essential features which would be of practical value to the participating mammography facilities. Helpful but non essential features include: generation of patient and physician letters, transcription function, ability to construct report based on findings present, pathology data fields, and capability to manage multiple mammography sites from central computer.

We anticipate many sites will adopt a computerized mammography management platform that will encode technologist and radiologist variables and periodically download this data to our centralized database. We hope to offer a system customized to meet the needs of the project as well as the individual sites at a reduced rate. This customized system would have the data entry screens on the computer match those on our paper forms for ease of entry. The concept of offering computerized options to facilities has appeal from many perspectives. It allows for autonomy of each facility in the collection and maintenance of interpretive data, greater capture of data, and decreased expense for ongoing data acquisition. Accuracy of data entry with a computer platform will be an issue facilities will have to consider, since the double data entry checks, which are part of the manual registry, will not be possible. We may then incorporate other quality assurance measures, since accuracy is so critical.

PILOT TEST PHASE I RESULTS

Between May 25th and October 15th a total of 2,406 women at pilot site facilities had a mammogram. Two thousand two hundred and sixty-two of these women gave consent to have their data entered into the registry (94%). These women have been entered into the patient registration system for tracking and linking purposes and their mammographic, risk factor and other demographic characteristics are currently being entered into the relational database. We are tracking 48 women who have received biopsy recommendations, 43 who's mammograms have been assessed as being highly suggestive of malignancy and 241 who's mammograms have been assessed as probably benign. The remaining 1930 mammograms were normal or normal with benign findings. Thirty-three women have received a recommendation for a clinical breast

exam, 31 have been referred to breast ultrasound and 30 have been referred for short interval follow-up. Of the 48 who have received biopsy recommendations, 15 pathology reports have come through the project. Of these seven (47%) have resulted in a diagnosis of breast cancer. Two (13%) were re-excisions of breast tissue to check for residual carcinoma. None was noted in either of these reports. Five (33%) pathology reports indicated women had benign breast disease (fibrocystic). There is a lag in timing from when the biopsy recommendations are made and when the pathology reports come through the Project office. We anticipate no difficulties in determining the outcomes of other breast biopsy recommendations.

CONCLUSIONS

At the conclusion of Year 1, we have successfully accomplished the tasks outlined in the original proposal. We are also working on a manuscript that will describe what we have learned about mammographic facilities in New Hampshire and how what we have learned can contribute to the discussions about developing a national mammography database registry. Our plans for Year 2 include completing testing phases of the paper data acquisition systems. We anticipate that those who opt for the computerized system will be higher volume sites (approximately 20) and that most sites will choose the paper system option. We will complete development and testing of the computer generated system and begin disseminating these systems to facilities. We will continue to maintain ongoing communication with facilities via Project newsletters and other correspondence and further develop the tracking strategies that will be required to monitor the status of women over time.

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APPENDICES

A. Pathology Quality Assurance Mini-proposal

B. Intake Form Completed by Participants

C. Facility Form Completed by Technologists

D. Mammography Form Completed by Radiologists

E. Pathology Form Completed by Pathologists

A NEW HAMPSHIRE REGIONAL PROJECT IN BREAST PATHOLOGY QUALITY ASSURANCE

Patricia A. Carney, PhD, Wendy A. Wells, MD

BACKGROUND AND SPECIFIC AIMS

Currently, histopathologic information is key in determining initial prognostic assessment and treatment for breast cancer (1). In addition, atypical hyperplasia is a borderline epithelial lesion, representing the most important histopathologic predictor of future breast cancer (2). Despite the importance of accuracy in pathologic assessment of breast tissue, a great deal of variability exists in intra- and inter observer agreement (3-5). This issue is especially important in cases where the potential health outcomes for women could be greatly affected. One such example is the well recognized difficulty in distinguishing between atypical ductal hyperplasia and ductal carcinoma in situ (DCIS) (5).

Several issues are likely to affect diagnostic accuracy in pathology. These include slide preparation for reading, methods for obtaining samples with potential for cell damage, and variability in pathology reading and reporting (6-9). The good news is that quality assurance programs, which include standardized reporting systems and joint review of slides has been shown to increase diagnostic accuracy in breast tissue pathology (9, 10).

New Hampshire is currently implementing a state-wide mammography registry. The specific focus of the registry is to increase mammographic screening effectiveness by creating a database that will allow for tracking of all women who receive a mammogram. Follow-up will include obtaining pathology reports on all breast tissue examined. Because accuracy in breast pathology is critical to the effectiveness of any breast screening program, implementing a quality assurance program in pathology will be important for the overall goals of the registry. No such program exists as part of the current mammography project plan. To address this issue, we propose to implement a regional program in breast pathology quality assurance.

The goals of this program are two-fold. First, we will conduct an assessment of variability in slide preparation, sample sources, and pathologic reporting, which will assist us in determining possible sources of discordance. Second, we will implement a quality assurance program that includes implementing a standardized reporting system and joint review of slides to enhance the diagnostic accuracy (quality and reproducibility) of breast pathology.

To achieve these goals, we propose to undertake the following specific aims:

1. To describe current practices in slide preparation, sample sources, and pathologic reporting in New Hampshire hospitals.
2. To determine the degree of inter- and intra observer agreement by pathologist in diagnostic assessment of breast tissue.
3. To explore the degree to which variability is associated with sample preparation, sample source, or diagnostic reading.
4. To improve diagnostic accuracy by implementing a quality assurance program.

Determining the degree of inter- and intra observer variability in pathology readings as well as factors that may be related to this will assist us in developing a program to enhance diagnostic accuracy in breast pathology. The importance of such a program for New Hampshire women lies in the potential increase in mammographic screening effectiveness potentially resulting in a decrease in breast cancer related morbidity and mortality. The goals of this

proposed project are completely in line with New Hampshire's state-wide mammography program.

STUDY METHODS

• Eligible Participants and Recruitment

All New Hampshire hospital-based pathologists interpreting breast tissue pathology will be targeted for participation in this project. Inclusion criteria will include: 1) licensed to practice in the State of New Hampshire; 2) practicing in a New Hampshire hospital; and 3) not planning on moving practice location within the next year. We anticipate approximately 23 pathologists will participate.

Physicians will be contacted by Wendy Wells, MD via telephone and be asked to take part. A fact sheet about the project and consent form will be mailed to each participant and follow-up will be conducted by Dr. Wells via telephone. All New Hampshire pathologists were contacted by Ben Littenburg, MD for enlistment of their participation in mammography registry activities, which includes sending reports on all breast tissue pathology to the registry. Though, we anticipate no problems with participation in the proposed project, reasons for either non-participation or exclusions will be collected.

• Data Collection Activities

Phase 1

The purpose of Phase 1 is to identify current practices in slide preparation, sample sources, and pathologist reporting (Specific Aim 1). All hospital laboratories will be queried about slide preparation protocols using a questionnaire developed for this purpose. Then, for a period of two months copies of all routine breast pathology reports (including sample sources) from each participating pathologist will be sent to the Project Coordinator at Dartmouth-Hitchcock Medical Center. The Coordinator will evaluate the completeness of the information provided, using a standardized data collection instrument developed specifically for this purpose. This instrument will be based on College of American Pathologists and Directors of Anatomic Pathology National Group Guidelines for slide preparation and reporting. We expect approximately 200 cases will be reviewed in this phase of the study.

Phase 2

The purpose of Phase 2 is to identify the degree of variability in pathology practices (Specific Aims 2 and 3). After the two months have passed, a summary of the College of American Pathologists and Directors of Anatomic Pathology National Group Guidelines will be provided to each pathologist. A random sample of breast biopsies cases will then be drawn from each laboratory and will be sent to the coordinator at DHMC. The mammography registry will be used to identify the random sample of breast biopsies.

The pathology coordinator will record the slides from each laboratory, cover any identifying slide labels and then send all the slides to each laboratory for independent evaluation using a universal data reporting form (Attachment A). All slides will be batched and sent around twice in a rotating and an unidentified manner each time, so that they are double read in a blinded fashion. The type of slides selected and methods for batching and rotating of slides will be done in such a manner as to replicate common pathology practices in New Hampshire. The universal data reporting forms will be returned to the coordinator, who will assign a unique identifier to each pathologist. The diagnoses from all submitted cases will be recorded and the results sent back to the participating pathologists for comparison. For example: pathologists E, D and G may diagnose a biopsy as ductal hyperplasia with atypia and pathologists B and A may diagnose a biopsy as ductal hyperplasia without atypia. We anticipate 50 slides representing 25 cases will be circulated.

Phase 3

The purpose of Phase 3 is to implement and assess the impact of a quality assurance program on pathology practices (Specific Aim 4). Four review meetings will be held during the study time period. Continuing Medical Education creidts will be given to all in attendance. All participating pathologists will review the discordant cases, discuss the discrepancies, and acquire an agreed upon set of criteria for certain diagnoses. After the last review meeting is complete, a second round of randomly selected slides will be obtained from participating pathologists over another two month period. Methods for slide selection and number, batching and sending will be identical to those used in Phase 2, though all cases and slides will be from different samples. The same universal data reporting form will be used for data collection purposes.

• Data Analysis

All data will be reviewed for completeness and entered into a database for evaluation. The Kappa Coefficient (percent agreement adjusted for chance) will be used to evaluate the degree of concordance between different observers for each slide read and the same observer on blinded double read slides. Variability in readings will be assessed by pathologist and by laboratory site. Individual and aggregate (blind) results will be reported back to each pathologist. In addition they will receive results by facility (blind). Assessment of the quality assurance program will be made by comparing Phase 2 Kappas with those collected during Phase 3.

• Human Subjects

Institutional Review Board approval would be obtained before this project would be conducted. All participants will be informed about the project and what their participation would specifically involve. They would also be informed that they could withdraw from participation at any time during the project time period.

• Timeline

We expect the project will take approximately one year to complete. Recruitment activities will take approximately one month. Phase 1 will take approximately two months, Phase 2 will take an additional two months to complete, and Phase 3 will take approximately four months, and data analysis will take approximately 2 months.

	Project Month											
Project Activities	1	2	3	4	5	6	7	8	9	10	11	12
Recruitment	X	------X										
Phase 1 •Submission of slides for completeness of information review		X	----------	X								
Phase 2 •Routing and review of randomly selected slides 1st Occasion				X	----------	X						
Phase 3 •Review Meetings						X	X	X	X			
•Routing and review of randomly selected slides 2nd Occasion								X	----------	X		
Data Analysis									X	----------	X	

BUDGET JUSTIFICATION (See budget for dedicated amounts)

• PERSONNEL

Patricia A. Carney, PhD Principal Investigator - 10%
Dr. Carney is the director for the New Hampshire Regional Breast Cancer Screening Network and a health services researcher. She would over all Project activities and maintain fiscal responsibility.

Wendy Wells, MD - Co-investigator - 10%
Dr. Wells is the pathologist liaison for the New Hampshire Regional Breast Cancer Screening Network. She would serve as pathology liaison and recruit pathology practices for participation. She would also organize and host the review meetings.

TBN Data Analyst - 10%
Mr. Swartz will over see all data entry and analysis activities.

TBN - DHMC Pathology Coordinator - 50%
This to be named individual will be responsible for coordinating all DHMC pathologydata collection activities.

TBN - Administrative Assistant - 5%
This to be named individual would be responsible for coordinating all recruitment activities and pathology meeting activities for Phase 3.

• OTHER

Review Meetings (n=4)
$1500 per meeting for meals, conference space and materials

Postage
For all correspondance and slide and case rotations.

Materials and Supplies
All pathology equipment including padded mailers, and equipment for handling incoming and outgoing slides.

Photocopy
Of all data collection instruments

Data Entry and Analysis
Entry of all study instruments.

Indirect cost rate had been negotiated from 62% to 35%.

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MAMMOGRAPHY FACILITY MUST COMPLETE

Patient's Hospital / Medical Record #: _____

Patient's Date of Birth: ____ - ____ - ____ (MM DD YY) Patient's Telephone Number: ____ - ____ - ____ (Home Number)

NH Mammography Network Demographic and Risk Factor Data Collection Form

Patient's Name: _____ (Last First Middle)

Address: _____

_____

_____

Zip code: _ _ _ _ _

Today's Date: _ _ - _ _ - _ _ (month day year)

PLEASE CLEARLY PRINT ALL INFORMATION

Please read the information below before you fill out the attached survey.

Information about the New Hampshire Mammography Network Project

Your mammography center is working with the Norris Cotton Cancer Center and Dartmouth Medical School to develop a registry (a computer database) of mammograms that will help us understand breast problems, including breast cancer. This registry is called the New Hampshire Mammography Network.

We are asking you to be a part of this research project. The attached survey is for research purposes only. It is not part of your routine procedure for mammography. **Your participation is strictly voluntary. Whether you participate or not, your decision will have no effect on your medical care.**

The information you provide to us in the attached survey and your mammography results will be entered into our New Hampshire Mammography Network. If you are a resident of Vermont, your information will be transferred to a similar mammography registry in Vermont. Neither our registry nor the Vermont registry will release any information that allows you to be identified. However, data collected through this project may be shared with other investigators, but without revealing your name or other identifying information.

If, after your mammogram, you have any further diagnostic studies or treatment related to breast problems, we may need to review your medical records to help us fully understand your mammography results. We also may contact you by mail or telephone to ask for more information.

Please Note: If there are any questions on the survey that you do not wish to answer, simply leave them blank. If you do not wish to participate in this research study, please hand all the forms back to the receptionist or mammography technologist.

If you have any questions regarding the NH Mammography Network Project, please call the Norris Cotton Cancer Center at 603-650-4135. Ask to speak with Karen Burgess or Patricia Carney.

Permission: We need your permission to use your data in our project, to obtain additional information from your medical records, and to contact you by phone or mail, if needed. Please sign here to indicate that you are willing to participate fully in these activities.

Signature: _____

NEW HAMPSHIRE MAMMOGRAPHY NETWORK USE ONLY: FACILITY CODE:
PATIENT ID:____

Have you ever completed a questionnaire like this one for the N.H. Mammography Network ?

[ ] Yes
[ ] No

To ensure accurate, up to date records, please complete the following questionnaire, **even if you answered yes to the preceding question.** Indicate your response by making a check mark in the box beside your selection. Thank you!

THIS FIRST SET OF QUESTIONS ASKS ABOUT YOUR MAMMOGRAM HISTORY:

1.0 Did you make your mammography appointment today because:

[ ] SCREENING ONLY/ NEITHER you or your doctor or health care provider have a concern about a breast difficulty. (lump, pain, etc.)

[ ] YOU were concerned about a breast difficulty?

[ ] YOUR DOCTOR or other health care provider was concerned about a breast difficulty?

[ ] BOTH you and your doctor or other health care provider were concerned about a breast difficulty?

1.1 Have you ever had a mammogram?

[ ] Yes
[ ] No

1.2 If Yes,

a) How many mammograms have you had in the last five years? (**not including your mammogram today**)

_____ # of mammograms

b) How old were you when you had your first mammogram?

_____ years of age

1.3 When did a doctor or health practitioner last examine your breasts?

[ ] within the last year

[ ] 1-2 years ago

[ ] about 3 years ago

[ ] 4-5 years ago

[ ] more than 5 years ago

[ ] Never

THE NEXT SET OF QUESTIONS ASK YOU ABOUT YOUR GENERAL HEALTH:

2.0 In general, would you say your health is:

[ ] Excellent
[ ] Very good
[ ] Good
[ ] Fair
[ ] Poor
[ ] Don't know

2.1 In the past four weeks, to what extent did health problems limit you in your everyday physical activities such as walking and climbing stairs?

[ ] Not at all
[ ] Slightly
[ ] Moderately
[ ] Quite a bit
[ ] Extremely
[ ] Don't know

2.2 How much bodily pain have you generally had during the past four weeks?

[ ] None at all
[ ] Very mild
[ ] Mild
[ ] Moderate
[ ] Severe,
[ ] Very severe
[ ] Don't know

2.3 During the past four weeks, how much have you been bothered by emotional problems such as feeling anxious, depressed, irritable, or downhearted and blue?

[ ] Not at all
[ ] Slightly
[ ] Moderately
[ ] Quite a bit
[ ] Extremely
[ ] Don't know

2.4 During the past four weeks, how much difficulty did you have doing your daily work (activities), both inside and outside the house, because of your physical health or emotional problems?

[ ] None at all
[ ] A little bit
[ ] Some
[ ] Quite a bit
[ ] Could not do dailywork/activities
[ ] Don't know

2.5 During the past four weeks, to what extent has your physical and emotional health interfered with your social activities with family, friends, neighbors, or groups ?

[ ] Not at all
[ ] Slightly
[ ] Moderately
[ ] Quite a bit
[ ] Extremely
[ ] Don't know

Appendix C

New Hampshire Mammography Network - Patient Intake Form

Facility Code: _ _ _ _ _ Today's Date: ___-___-___ (MM - DD - YY) Referring Physician: _____

Patient Name: _____ Last First Middle Initial Patient's ZIP Code: _____

Social Security #: ___-___-___ [For Data Links Only] Date of Birth: ___-___-___ (MM - DD - YY)

Patient's Tel. Number: (___) ___-____

DID PATIENT READ AND SIGN THE NHMN SURVEY CONSENT FORM? [ ] YES

HAS PATIENT HAD A PREVIOUS MAMMOGRAM ?

[ ] NO [ ] YES Date of last mammogram? (MM - DD - YY) ___-___-___ Location: _____

Town: _____ State: _____

DOES PATIENT HAVE ANY BREAST CONCERNS? How long has there been concern? (number of months) _____

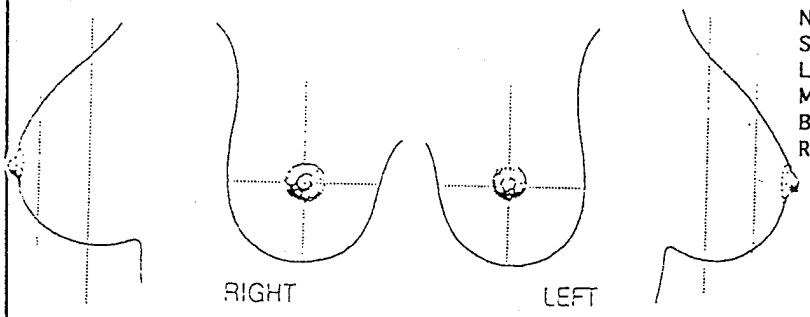
[ ] NO [ ] YES Who first became concerned? [ ] Self [ ] Partner [ ] Physician/Nurse

Type of Concern:	Left	Right
Lump	[ ]	[ ]
Nipple Discharge	[ ]	[ ]
Skin changes	[ ]	[ ]
Other (Please specify)	[ ]	[ ] _____

DID PATIENT HAVE ANY PAST BREAST PROCEDURES?

[ ] NO [ ] YES

Type of Procedure:	Left	Right	Month/Year
Breast Reduction	[ ]	[ ]	____/____
Breast Implants	[ ]	[ ]	____/____
Needle Biopsy	[ ]	[ ]	____/____
Surgical Biopsy	[ ]	[ ]	____/____
Lumpectomy	[ ]	[ ]	____/____
Mastectomy	[ ]	[ ]	____/____
Breast Reconstruction	[ ]	[ ]	____/____
Radiation Therapy	[ ]	[ ]	____/____ (Date of Completion)



Please indicate on the pictures any area of concern or past procedure

Comments: _____

HAS PATIENT EVER HAD BREAST CANCER ?

[ ] NO [ ] YES Age at diagnosis? ____ years Which Breast? [ ] Left [ ] Right

DOES PATIENT HAVE A FAMILY HISTORY OF BREAST CANCER?

[ ] NO [ ] YES

	Under 50	Over 50
Mother	[ ]	[ ]
Sister	[ ]	[ ]
Daughter	[ ]	[ ]
Maternal Aunt	[ ]	[ ]
Maternal Grandmother	[ ]	[ ]

AGE AT FIRST MENSTRUAL PERIOD? ____ years

HAVE PERIODS STOPPED?

[ ] NO [ ] YES What Age? ____ years

DID PERIODS STOP DUE TO:

[ ] Menopause
[ ] Birth Control/Hormones
[ ] Surgery (Hysterectomy)
[ ] Radiation Therapy
[ ] Chemotherapy
[ ] Other (Please specify) _____

HAS PATIENT EVER TAKEN HORMONE REPLACEMENT?

[ ] NO [ ] YES, CURRENTLY TAKING _____ For how long?
[ ] YES, HAS TAKEN IN THE PAST

[ ] Premarin [ ] Tamoxifen
[ ] Provera [ ] Other (specify) _____
[ ] Birth control

HAS THE PATIENT HAD AN OVARY REMOVED?

[ ] NO [ ] YES
[ ] One Ovary
[ ] Both Ovaries
[ ] Don't know if one or both
[ ] Don't Know

How old was patient when she had an ovary removed? _____

HOW MANY PREGNANCIES HAS PATIENT HAD?

[ ] NONE [ ] Total
[ ] Live births [ ] Miscarriages
[ ] Stillbirths [ ] Abortions

How old was patient when her first child was born? _____

DOES PATIENT ROUTINELY PRACTICE BSE? [ ] NO [ ] YES

Appendix D

New Hampshire Mammography Network

Mammographic Variables Pilot Data Collection

Code:

Please Print

1. Patient Name: _____ (Last) _____ (First) _____ (Middle Initial) Exam Date: (MM - DD - YY) _____ Date of Birth: (MM - DD - YY) _____

Social Security #: _____ - _____ - _____ Patient's ZIP Code: _____ Referring Physician's Name & Town: _____

Tech. Initials: _____ Rad. Initials: _____ Rad.Code: _____ Facility Code: _____

Patient's Medical Record #: _____ (For NHMN Use only)

2. Type of Exam: (Please check all that apply)

	Both	Left only	Right only
[ ] Asymptomatic (Screening) Mammogram		[ ]	[ ]

	Left	Right	Both
Baseline Mammogram	[ ]	[ ]	[ ]
Screening and Additional Views	[ ]	[ ]	[ ]
Diagnostic Mammogram	[ ]	[ ]	[ ]
Short Interval Follow-up (3 - 6 months)	[ ]	[ ]	[ ]
Additional Views (immediate evaluation)	[ ]	[ ]	[ ]

3. Were Comparison Films used for Interpretation? ☐ Yes ☐ No

4. Breast Composition:

[ ] Fat [ ] Scattered [ ] Heterogenously Dense [ ] Extremely Dense

5. Assessment Status: Check ☐ if Breast Ultrasound* was used to complete the assessment status.

	Both	Left only	Right only
[ ] Negative		[ ]	[ ]

	Left	Right	Both
Assessment Incomplete	[ ]	[ ]	[ ]
Benign Finding - Negative	[ ]	[ ]	[ ]
Probably Benign Finding	[ ]	[ ]	[ ]
Suspicious Abnormality †	[ ]	[ ]	[ ]
Highly Suggestive of Malignancy †	[ ]	[ ]	[ ]

* Please complete Ultrasound Report on back

† For Assessments where status is coded S or M, please complete Finding Report on back

6. Recommendation:

	Both	Left only	Right only
[ ] Routine Screening Mammogram		[ ]	[ ]

	Left	Right	Both	
Short Interval Mammographic Follow-Up	[ ]	[ ]	[ ]	in ____ Months
Biopsy (Including Fna)	[ ]	[ ]	[ ]	

Check ☐ if Immediate Additional Assessment is required and indicate below:

	Left	Right	Both
Diagnostic Mammography	[ ]	[ ]	[ ]
Breast Ultrasound	[ ]	[ ]	[ ]
Clinical Breast Exam	[ ]	[ ]	[ ]

7. Finding 1:

☐ Left Breast
☐ Right Breast

Type:	Size (mm):	Margins (Mass only):	Distribution (Calcs only):
☐ Mass	☐ 1- 9	☐ Sharp	☐ Cluster
☐ Calcification	☐ 10-19	☐ Obscured	☐ Linear
☐ Density	☐ 20-49	☐ Indistinct	☐ Segmental
☐ Architectural Distortion	☐ >=50	☐ Spiculated	☐ Regional

8. Finding 2:

☐ Left Breast
☐ Right Breast

Type:	Size (mm):	Margins (Mass only):	Distribution (Calcs only):
☐ Mass	☐ 1- 9	☐ Sharp	☐ Cluster
☐ Calcification	☐ 10-19	☐ Obscured	☐ Linear
☐ Density	☐ 20-49	☐ Indistinct	☐ Segmental
☐ Architectural Distortion	☐ >=50	☐ Spiculated	☐ Regional

9. Ultrasound Report:

	Left	Right	Both
No Abnormality Detected	[ ]	[ ]	[ ]
Simple Cyst	[ ]	[ ]	[ ]
Complex Cyst	[ ]	[ ]	[ ]
Solid Mass	[ ]	[ ]	[ ]

10. Other Benign Findings (Optional):

	Left	Right	Both
Multiple Masses	[ ]	[ ]	[ ]
Surgical Scar	[ ]	[ ]	[ ]
Radiation Change	[ ]	[ ]	[ ]
Breast Implant(s)	[ ]	[ ]	[ ]

11. Additional Comments (Optional):

Appendix E

New Hampshire Mammography Network

Pathology Follow-Up Form

NHMN Code:_____

Please Print

1. Laboratory Code: _____ Patient Name: _____
Last First Middle Initial

Patient's Date of Birth: ____ - ____ - ____
(MM - DD - YY)

Patient's Medical Record #: _____

Pathology Code: _____

1.2 Date of Bx/FNA: ____ - ____ - ____
(MM - DD - YY)

1.3 Physician performing Bx/FNA: _____

1.4 Institution Bx/FNA performed: _____

2. Have Previous Breast Biopsies been done?

☐ No ☐ Yes

2.1 Date done: ____ - ____ - ____
(MM - DD - YY)

2.2 Institution: _____

2.3 Surgical Number: _____

2.4 Diagnosis: _____

3. Current Breast Specimen :

	Left	Right	Both
3.1 Excisional biopsy	☐	☐	☐
3.2 Mastectomy	☐	☐	☐
3.3 Axillary contents	☐	☐	☐
3.4 Needle localization BX	☐	☐	☐
3.5 US guided core needle	☐	☐	☐
3.6 Stereotactic core needle	☐	☐	☐
3.7 Palpation core Bx	☐	☐	☐
3.8 Fine needle aspiration	☐	☐	☐

4.00 - 6.00 Diagnostic Interpretation:

4.0 Unsatisfactory:

4.1 No breast parenchyma present (HISTOLOGY) ☐
4.2 Less than 5 groups of ductal epithelial cells (CYTOLOGY) ☐
4.3 No microcalcifications seen in core needle (if on mammo.) ☐
4.4 Suboptimal tissue evaluation due to:
4.4.1 Poor tissue preservation/fixation ☐
4.4.2 Section/smear thickness ☐
4.4.3 Staining ☐

5.0 Benign:

5.1 Fibroadenoma ☐
5.2 Fibrocystic changes:
(apocrine metaplasia, adenosis, sclerosing adenosis, cysts): ☐
5.3 Hyperplasia without atypia :
5.3.1 DUCTAL ☐
5.3.2 LOBULAR ☐
5.4 Hyperplasia with atypia :
5.4.1 DUCTAL ☐
5.4.2 LOBULAR ☐
5.5 Other: _____ ☐

6. Malignant:

6.1 CARCINOMA-IN-SITU:

- 6.1.2 Lobular CIS ☐
- 6.1.3 Ductal CIS ☐
  - 6.1.4 Comedo ☐
  - 6.1.5 Non-comedo ☐

6.2 INVASIVE CARCINOMA:

- 6.2.1 Infiltrating ductal ☐
- 6.2.2 Infiltrating lobular ☐
- 6.2.3 Other ☐

7.0 Histologic/Nuclear GRADE:

- 7.1 **Well** differentiated (Grade I/SBR Scale (3-5) ☐
- 7.2 **Moderately** differentiated (Grade II/SBR Scale (6-7) ☐
- 7.3 **Poorly** differentiated (Grade III/SBR Scale (8-9) ☐

8.0 SIZE of Lesion : _____ x _____ x _____ (cm)

9.0 ANGIOLYMPHATIC Invasion:

☐ No ☐ Yes

10.0 MARGINS of excision involved :

☐ No ☐ Yes If Yes, 10.1 By in-situ carcinoma ☐
10.2 By infiltrating carcinoma ☐

11.0 AXILLARY LYMPH NODES:

☐ No ☐ Yes If Yes, 11.1 Positive # _____
11.2 Negative # _____

12.0 PAGET'S DISEASE:

☐ No ☐ Yes

13.0 MICROCALCIFICATIONS PRESENT:

☐ No ☐ Yes If Yes, 13.1 Benign Association: ☐
13.2 Malignant Association: ☐
13.3 In situ carcinoma ☐
13.4 Infiltrating carcinoma ☐